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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/320,100 05/26/99 ANSALDI

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EXAMINER

HM12/0522

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HUNT, J

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/320,100

Applicant(s)
Ansaldi et al.

Examiner
Jennifer Hunt

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 7, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 3/07/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/320,100 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-13 are pending in the application.

Claim Rejections Maintained/New Grounds of Rejection

2. The grounds of rejection of claims 1-2, 5-7, and 9-13 under U.S.C. 102(b) as being anticipated by Yang et al., Journal of Chromatography, A743, 1996 is maintained for reasons of record.

Applicant argues that Yang et al. is not applicable to the instantly claimed invention because Yang et al. teaches separating polypeptide monomers from other monomeric forms thereof (such as differentially glycosylated or post-translationally different IgGs) or from totally different polypeptide monomers contained in ascites and sera, and further contains no explicit or inherent disclosure of separation of monomers from their own dimers or multimers. Applicant further argues that Yang et al.'s figures and teachings indicate that the methods of Yang et al. do not separate monomers from their own dimers or multimers. Applicant's arguments filed 3-07-2001 have been fully considered but they are not persuasive.

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The method of Yang et al. is a protein purification method which is identical to the claimed method. In general, Yang et al. teaches a method of using ion exchange chromatography to purify proteins, and further teaches that this method provides many advantages over other art know protein purification techniques. Specifically, as set forth in the previous office actions, Yang et al. teaches a method of applying a mixture (which includes IgG's, ascites and sera, see abstract and examples 3.6.1 and 3.6.2) to a cation exchange chromatography resin with numerous pH's in the 6-7 range or a anion exchange resin with numerous pH's in the 6-9 range.(pages 173-177). Yang et al. details numerous ion exchange techniques, and tests different aspects of these techniques. Yang et al. also uses the method to separate monomers from a mixture of dimers and multimers (serum and ascites).

The method steps of Yang et al. are identical to the instantly claimed method, regardless of what type of molecule is sorted, or purified, or what it is sorted or purified from. Thus because the methods are identical, the properties of the purification method are inherent. Thus, although Yang et al. does not teach specifically that monomers are separated from dimers and/or multimers of the monomers, the method would inherently posses this property. Further, since the method of Yang et al. is a method of purifying proteins, and the limitations recited in the instant claims are drawn to a protein purification method, one of skill in the art would expect that the identical protein purification methods would function in identical ways, and thus absent evidence to the contrary, would be effective to purify monomers from dimers and multimers of the monomers, and would result in the same levels of purity.

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3. The grounds of rejection of claims 1-2, 5-7, and 9-13 under U.S.C. 102(a) as being anticipated by Hahn et al., *Chromatography*, 795, pages 277-287 (1998) is maintained for reasons of record.

Applicant argues that Hahn et al. is not applicable to the instantly claimed invention because Hahn et al. teaches separation of various proteins from each other, and that there is no evidence in Hahn et al. of separation of monomers from their own dimers or multimers.

Applicant's arguments filed 3-07-2001 have been fully considered but they are not persuasive.

Applicant provides no evidence to support the assertion that the mixture taught in Hahn et al. does not contain dimers and/or multimers of its own monomers. Furthermore, Hahn et al. teaches purification of immunoglobulins using an identical method to that instantly claimed, and thus "purification" would include elution of the IgG monomers from a mixture (bovine whey) which contains monomers and dimers or multimers. Further, both methods are drawn to protein purification, and thus, as set forth above, would inherently function in the specific protein purification method of separating monomers from dimers and multimers of the monomer, and would result in the same levels of purity.

4. The grounds of rejection of claims 1-2 and 4-13 under 35 U.S.C. 103(a) as being unpatentable over Yang et al., in view of US Patent 4,764,279, Tayot et al is maintained for reasons of record.

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Applicant argues that Tayot fails to overcome the deficiencies of Yang et al. and fails to teach separation of a monomer from a mixture of monomers and dimers. Applicant's arguments filed 3-7-2001 have been fully considered but they are not persuasive.

Applicant's arguments regarding Yang et al. have been addressed supra. As set forth previously, the mixture of Tayot is blood and thus would contain dimers and multimers inherently. Furthermore, as set forth above, one of skill in the art would reasonably expect that a method useful for purifying proteins which is identical in method steps to the instant method would function identically as well, and thus perform the specific purification of monomers from dimers and multimers of the monomer, and would result in the same levels of purity which are instantly claimed.

5. The grounds of rejection of claims 1-3 and 5-13 under 35 U.S.C. 103(a) as being unpatentable over Yang et al and Hahn et al., in view of Oncogene Science catalog 1992, pages 18 and 35 is maintained for reasons of record.

Applicant argues that Oncogene Science fails to overcome the deficiencies of Yang et al. and Hahn et al, and fails to teach separation of a monomer from a mixture of monomers and dimers. Applicant further argues that the Oncogene science antibodies are already purified, and thus would not require the instant purification method. Applicant's arguments filed 3-7-2001 have been fully considered but they are not persuasive.

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Applicant's arguments regarding Yang et al., and Hahn et al. have been addressed supra. With regard to applicant's argument that the mixture in Oncogene Science does not contain monomers, the reference is submitted to set forth the desirability of purification of the specific antibodies of claim 3. As set forth in previous office actions, it is not necessary that the claimed invention be expressly suggested by in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to one of ordinary skill in the art. (*In re Keller*, 642 F.2d 413,288 USPQ 871 9ccpa 1981). Specifically, the reference is supplied to teach the desirability of the purification process: that purified antibodies are commercially desirable, which as applicant has pointed out, the reference clearly sets forth.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

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Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

May 21, 2001


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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